

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
AUSTIN DIVISION**

FILED

DEC 7 2004

CLERK, U.S. DISTRICT COURT  
WESTERN DISTRICT OF TEXAS  
BY *SM*

**UNITED STATES OF AMERICA.**

10

(i) RICHARD J. ADLER, and

(2) LINDA K. SHAFFER,

**Defendants.**

WESTERN DISTRICT OF TEXAS  
BY JW DEPUTY CLERK

## THE GRAND JURY CHARGES:

## **INTRODUCTION**

At all times relevant to this Indictment:

1. The United States Food and Drug Administration ("FDA") was the agency of the United States responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et seq.* The FDA's responsibilities included regulating the manufacture, labeling, and distribution of prescription drugs shipped or received in interstate commerce.

2. Under the FDCA, drugs were defined as, among other things, articles intended for use in the cure, mitigation, treatment or prevention of disease in man; articles intended to affect the structure or function of the body of man; and articles intended for use as components of other drugs. 21 U.S.C. §321(g)(1)(B)-(D).

3. Under the FDCA, the term "label" was defined as a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k).

4. Under the FDCA, the term "labeling" was defined as all labels and other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

5. Under regulations implementing the FDCA, the term "labeling" was further defined to include, among other items, brochures, booklets, mailing pieces, detailing pieces, letters, or pieces of printed, visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of the manufacturer, packer, or distributor. 21 C.F.R. § 202.1(l)(2).

6. The term "manufacture, preparation, propagation, compounding, or processing" included repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. 21 U.S.C. § 360(a)(1). *cf. MM&P*

7. A drug was misbranded under the FDCA if, among other things:

a. its labeling was false or misleading in any particular (21 U.S.C. 352(a));

b. the labeling on the drug did not bear adequate directions for use (21 U.S.C. § 352 (f)(1));

c. the labeling on the drug did not bear such adequate warnings against use in those pathological conditions, and by children where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration and application, in such manner and form, as were necessary for the protection of users (21 U.S.C. § 352(f)(2)); and

d. if it was manufactured, prepared, propagated, compounded or processed in an establishment in any State not duly registered under 21 U.S.C. § 360 (21 U.S.C. § 352(o)).

8. The FDCA prohibited the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of any misbranded drug. 21 U.S.C. § 331(a).

9. Under the FDCA, a "prescription drug" was, among other things, a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or a drug which was limited by an approved application under 21 U.S.C. § 355 to use under the professional supervision of a practitioner licensed by law to administer such drug. 21 U.S.C. § 353(b)(1).

10. Under the FDCA, "wholesale distribution" meant distribution of prescription drugs to other than the consumer or patient, but did not include intra-company sales or the distribution of drugs pursuant to the terms of 21 U.S.C. §353(c)(3)(B).

11. The FDCA prohibited engaging in the wholesale distribution in interstate commerce of prescription drugs in a State by persons who are not licensed by the State. 21 U.S.C. § 353(e)(2)(A).

12. The FDCA also prohibited the knowing distribution of, or possession with intent to distribute, human growth hormone ("hGH") for any use in humans other than the treatment of a disease or other recognized medical condition that had been authorized by the Secretary of the United States Department of Health and Human Services ("HHS") and that was pursuant to the order of a physician. 21 U.S.C. § 333(e).

13. The term hGH meant somatrem, somatropin, or an analogue of either somatrem or somatropin. 21 U.S.C. § 333(e)(4). Somatrem was an analog of somatropin. Somatropin was a synthetic or naturally occurring growth hormone from the human pituitary gland.

14. All hGH were prescription drugs because of their toxicity or other potentiality for harmful effect, or the method of their uses, or the collateral measures necessary to their uses, were not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Those hGH products that were approved for use by the FDA pursuant to 21 U.S.C. § 355 were limited to the specific approved use and only under the professional supervision of a practitioner licensed by law to administer prescription drugs. 21 U.S.C. §§ 353(b)(1)(A) and (B).

15. The only uses of FDA-approved hGH drugs that had been authorized by the Secretary of HHS were for the treatment of the following:

- a. short stature in children with growth hormone deficiency (GHD);
- b. short stature in children with idiopathic short stature;
- c. short stature in children with Turner syndrome;

- d. short stature in children with chronic renal insufficiency prior to renal transplantation;
- e. short stature in children with Prader-Willi syndrome;
- f. short stature in children who were born small for gestational age and failed to "catch-up;"
- g. adults with biochemically documented growth hormone deficiency ("AGHD"), diagnosed either in adulthood (so-called adult onset AGHD) or previously diagnosed in childhood and reconfirmed as an adult (so-called childhood onset AGHD);
- h. adults with wasting/cachexia associated with human immunodeficiency virus (HIV) infection; and
- i. adults with short bowel syndrome (SBS).

16. The FDA did not approve the use of any hGH product for use in anti-aging or longevity treatment for adults.

#### THE DEFENDANTS

17. Defendant RICHARD J. ADLER was a practicing physician in the State of New York. Defendant ADLER moved to Mallorca, Spain, and became the owner and operator of PROMOCIONES ES CLOT de DAYA. From Mallorca, Spain, Defendant ADLER promoted, sold and distributed hGH in the United States for use in the cure, mitigation, treatment or prevention of anti-aging or longevity, a use that was not authorized by the Secretary of HHS.

18. Defendant LINDA SHAFFER, the daughter of defendant RICHARD ADLER, received, labeled, and distributed hGH throughout the United States using commercial carriers, such as DHL.

**COUNT 1****(Conspiracy - 18 U.S.C. § 371)**

19. The factual allegations of paragraphs 1 through 18 above are realleged and incorporated herein by reference.

20. Beginning at a time unknown to the Grand Jury, but at least as early as in or about December 1999, and continuing through at least in or about April 2004, defendants RICHARD ADLER and LINDA SHAFFER, aided and abetted by others known and unknown, did knowingly and willfully agree and conspire with others, known and unknown to the Grand Jury, to commit the following offenses against the United States in the Western District of Texas and elsewhere:

- a. Knowingly distributing hGH for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of HHS under Title 21, United States Code, Section 355, and pursuant to the order of a physician, in violation of Title 21, United States Code, Section 333(e)(1), and Title 18, United States Code, Section 2;
- b. Introducing and causing the introduction into interstate commerce of misbranded drugs with the intent to defraud and mislead, in violation of Title 21, United States Code, Sections 331(a), 352(a), 352(f) and (o), and 333(a)(2), and Title 18, United States Code, Section 2; and
- c. Knowingly engaging in the wholesale distribution of a prescription drug without a State license in violation of Title 21, United States Code, Sections 331(t), 353(e)(2)(A), and 333(b)(1)(D), and Title 18, United States Code, Section 2.

A. Manner and Means of the Conspiracy

21. The manner and means employed by the defendants to effect the objects of the conspiracy were as follows:

- a. Defendant RICHARD ADLER, with the assistance of suppliers in China, caused vials of a drug containing hGH to be manufactured in China.
- b. Defendant RICHARD ADLER sent out letters by electronic mail ("e-mail") and United States Mail to physicians and individuals related to the health-care profession in the United States that promoted the sale of a drug containing hGH for use in anti-aging or longevity care, and set forth information about the drug containing hGH.
- c. Suppliers in China caused vials of a drug containing hGH that was manufactured in China to be delivered from China to defendant RICHARD ADLER in Mallorca, Spain.
- d. Defendant RICHARD ADLER then caused a drug containing hGH to be delivered from Spain to physicians and other people related to the health-care profession in the United States, including the Western District of Texas.
- e. In addition, Defendant RICHARD ADLER, with the assistance of suppliers in China, caused vials of a drug containing hGH that were manufactured in China to be delivered from China to defendant LINDA SHAFFER in the United States, or to other individuals in the United States who received the deliveries on behalf of defendant LINDA SHAFFER.
- f. Upon receiving or obtaining the shipments, defendant LINDA SHAFFER placed labels upon the vials of the drug containing hGH and distributed the drug to physicians and their representatives throughout the United States, including the Western District of Texas.

**B. Overt Acts**

22. In furtherance of the aforesaid conspiracy, and to effect the objects of the conspiracy, the defendants and the suppliers in China committed or caused to be committed the following overt acts:

- a. On or about September 2, 1997, defendant RICHARD ADLER contacted an individual in China, hereinafter referred to as "Supplier #1," by e-mail to determine whether Supplier #1's company in China was interested in supplying hGH for sale and distribution in the United States and Europe.
- b. On or about September 2, 1997, defendant RICHARD ADLER sent an e-mail to Supplier #1 advising Supplier #1 of "the complex problems that I face in trying to get this product into the hands of my professional clients in the United States." Defendant ADLER further advised Supplier #1 that the hGH manufactured in China "is not approved by the FDA (Federal Drug Administration), and this creates a series of problems that I must solve."
- c. On or about September 4, 1997, defendant RICHARD ADLER and Supplier #1 exchanged e-mails, in which defendant ADLER agreed to pay \$25,750 in United States ("U.S.") currency for every 5000 vials of hGH manufactured in China.
- d. On or about January 26, 1998, and February 13, 1998, defendant RICHARD ADLER sent e-mails to Supplier #1 discussing defendant ADLER's trip to China in February 1998, to meet with Supplier #1.
- e. On or about June 26, 1998, defendant RICHARD ADLER drafted a letter to Supplier #1 "to confirm . . . [an] agreement for the production in China of Norditropin HGH (somatropin) which is for export outside of the People's Republic of China" and "that this product,

produced in China, is produced and packaged according to the formulation and packaging provided by my company."

f. On or about October 15, 1999, defendant RICHARD ADLER sent an e-mail to an individual in the United States, promoting the sale of his hGH product, in which defendant Adler claimed to have been supplying hGH "to the Longevity industry" for "the past several years" and further stating that the hGH he was supplying was "a European generic HGH."

g. On or about October 16, 1999, defendant RICHARD ADLER sent an e-mail to a Special Agent of FDA's Office of Criminal Investigations (FDA/OCI) posing as a pharmacist to promote the sale of defendant ADLER's hGH product. Defendant ADLER stated in the e-mail that he is supplying the hGH for "the Longevity market," although acknowledging that "Longevity use is not FDA approved." Defendant ADLER further stated that he would ship the hGH "through a reliable Mexican transport company in order to avoid problems of entry through the American channels with usual possible conflicts with American customs and FDA."

h. On or about December 23, 1999, defendant RICHARD ADLER caused two parcels containing 500 vials of hGH to be sent by DHL from Mallorca, Spain, to an FDA/OCI Special Agent in Austin, Texas. The DHL airbill accompanying the parcels identified the contents of the parcels as, "Christmas Present Soap Candles Value \$20."

i. On or about December 22, 1999, defendant RICHARD ADLER caused vials of hGH to be sent by DHL to a physician in Corpus Christi, Texas. The DHL airbill accompanying the shipment identified the contents of the shipment as "Soaps and Candles."

j. Defendant RICHARD ADLER subsequently sent an e-mail to the physician in Corpus Christi, Texas, on or about January 7, 2000, requesting a bank wire transfer to his bank

account with Deutsche Bank in the amount of \$2600 for the hGH shipment that defendant ADLER sent to the physician.

k. On or about March 18, 2000, defendant RICHARD ADLER caused vials of hGH to be sent to a physician in Corpus Chiristi, Texas.

l. Defendant RICHARD ADLER subsequently sent an e-mail to the assistant of the physician in Corpus Christi, Texas, on or about March 18, 2000, requesting confirmation that the physician had received his hGH shipment and requesting a wire transfer in the amount of \$5200 from the physician's bank to defendant ADLER's.

m. On or about May 24, 2000, defendant RICHARD ADLER caused 250 vials of hGH to be sent by DHL to a physician in Corpus Christi, Texas.

n. On or about July 21, 2000, defendant RICHARD ADLER sent an e-mail to a physician in Corpus Chiristi, Texas, notifying him, among other things, that the hGH will now be labeled with a new generic label and that a shipping charge of \$75 will be added to each shipment.

o. From on or about July 24, 2000, to on or about April 1, 2003, defendants LINDA SHAFFER and RICHARD ADLER caused vials of hGH to be sent on various occasions by DHL to a physician in Corpus Christi, Texas.

p. From on or about July 24, 2000, to on or about April 1, 2003, defendant RICHARD ADLER sent e-mails to a physician in Corpus Christi, Texas, and/or the physician's assistant on various occasions notifying them that the physician's hGH order had been or would be sent out and requesting a wire transfer from the physician's bank account to defendant ADLER'S bank account.

q. On or about August 26, 2000, defendant RICHARD ADLER sent a letter via facsimile transmission to a physician in Corpus Christi, Texas, promoting the sale of his hGH product for "longevity care."

r. On or about September 27, 2000, defendant RICHARD ADLER sent an e-mail to defendant LINDA SHAFFER stating that, in order to stimulate more hGH sales, he contacted an individual working for the Academy of Anti-Aging Medicine to send out a second mailing to their membership.

s. On or about October 17, 2000, defendants LINDA SHAFFER and RICHARD ADLER caused 100 vials of hGH to be shipped by DHL from Massachusetts to a physician in Austin, Texas.

t. On or about October 25, 2000, and again on November 4, 2000, defendant RICHARD ADLER sent e-mails to the physician in Austin, Texas, requesting payment for the hGH shipment that was sent to the physician.

u. On or about October 28, 2000, defendant RICHARD ADLER caused a letter to be sent through the United States Mail to physicians in the United States advertising and promoting the sale of his hGH product.

v. On or about October 30, 2000, defendant RICHARD ADLER sent an e-mail to Supplier #2, an individual associated with Supplier #1, notifying him that he just sent out a marketing letter to ten thousand physicians in America who are members of the American Academy of Anti-Aging Medicine, and requesting that Supplier #2 send 1000 vials of the hGH to defendant LINDA SHAFFER.

w. On or about October 31, 2000, Supplier #2 sent an e-mail to defendant RICHARD ADLER stating that he sent 1000 vials of hGH to defendant LINDA SHAFFER by European Mail System ("EMS").

x. On or about November 5, 2000, defendant RICHARD ADLER sent defendant LINDA SHAFFER an e-mail stating that he was going to increase her payment to \$1500 per month from \$1000 per month for distributing hGH. In addition, defendant ADLER stated that defendant SHAFFER could earn an additional \$750 for every 500 vials she distributed in excess of 1000 vials.

y. On or about November 5, 2000, defendant LINDA SHAFFER sent an e-mail to defendant RICHARD ADLER, stating that her expenses per 1000 vials of hGH is approximately \$150.

z. On or about November 6, 2000, defendant LINDA SHAFFER sent an e-mail to defendant RICHARD ADLER stating that she had distributed 10,000 vials of hGH from May 2000, through October 2000.

aa. On or about November 6, 2000, defendant RICHARD ADLER sent an e-mail to an individual in Deer Park, Texas, requesting payment for a shipment of hGH.

bb. On or about November 6, 2000, defendant RICHARD ADLER sent an e-mail to Supplier #2 requesting that 1000 vials be sent to defendant LINDA SHAFFER.

cc. On or about November 7, 2000, Supplier #2 sent an e-mail to defendant RICHARD ADLER stating that the shipment had been sent out to defendant LINDA SHAFFER by EMS.

dd. On or about December 1, 2000, defendant LINDA SHAFFER shipped vials of hGH by mail via DHL to a physician and/or his assistant in Deer Park, Texas.

ee. On or about February 20, 2001, defendant RICHARD ADLER sent an e-mail to defendant LINDA SHAFFER, directing her to send 400 vials of hGH to a physician in Corpus Christi, Texas.

ff. On or about March 11, 2001, defendant LINDA SHAFFER sent an e-mail to defendant RICHARD ADLER to notify him that shipments of hGH were sent out to several individuals. Defendant SHAFFER also notified defendant ADLER in the same e-mail that she distributed 1700 vials of hGH in February 2001, and that her expenses for that month were \$200. In addition, Defendant SHAFFER notified defendant ADLER that she purchased \$350 worth of labels and received an extra 1000 labels.

gg. On or about August 16, 2002, and February 2, 2004, defendant LINDA SHAFFER shipped vials of hGH to a physician in Kirbyville, Texas.

hh. On or about August 16, 2002, defendant RICHARD ADLER sent an e-mail to the assistant of a physician in Kirbyville, Texas, to confirm that she received the vials of hGH that were sent to Kirbyville, Texas, and requested payment for the shipment.

All in violation of Title 18, United States Code, Section 371.

**COUNT 2**  
**(Distributing Human Growth Hormone for an Unauthorized Use)**

23. The factual allegations in paragraphs 1 through 18 of the Indictment are incorporated by reference and realleged as though fully set forth herein.

24. On or about December 23, 1999, defendant RICHARD ADLER, aided and abetted by others known and unknown, did knowingly distribute hGH to the Western District of Texas for use in the treatment of anti-aging or longevity, a use in humans that had not been authorized by the

Secretary of HHS under Title 21, United States Code, Section 355, and pursuant to the order of a physician, in violation of Title 21, United States Code, Section 333(e) and 18, United States Code, Section 2.

**COUNT 3**  
**(Introducing Misbranded Drugs into Interstate Commerce)**

25. The factual allegations in paragraphs 1 through 18 of the Indictment are incorporated by reference and realleged as though fully set forth herein.

26. On or about December 23, 1999, defendant RICHARD ADLER, aided and abetted by others known and unknown, with the intent to defraud and mislead, introduced and delivered for introduction into interstate commerce and caused to be introduced and delivered for introduction into interstate commerce for distribution to Austin, Texas, the prescription drug hGH that was misbranded in that its labeling was false or misleading in any particular, and in that it failed to bear adequate directions for use, all in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), 352(a), 352(f)(1), and Title 18, United States Code, Section 2.

**COUNT 4**  
**(Distributing Human Growth Hormone for an Unauthorized Use)**

27. The factual allegations in paragraphs 1 through 18 of the Indictment are incorporated by reference and realleged as though fully set forth herein.

28. On or about October 17, 2000, defendants RICHARD ADLER and LINDA SHAFFER, aided and abetted by others known and unknown, did knowingly distribute hGH to the Western District of Texas for use in the treatment of anti-aging or longevity, a use in humans that had not been authorized by the Secretary of HHS under Title 21, United States Code, Section 355, and pursuant

to the order of a physician, in violation of Title 21, United States Code, Section 333(e), and Title 18, United States Code, Section 2.

**NOTICE OF SPECIFIC FACTS RELEVANT TO SENTENCING**

For purposes of determining Defendant ADLER'S sentence under the United States Sentencing Guidelines, the Grand Jury alleges the following as to Count One through Count Four of this Indictment:

1. That the loss exceeded more than \$400,000 [See U.S.S.G. § 2B1.1(b)(1)];
2. That the offense involved 10 or more victims [See U.S.S.G. § 2B1.1(b)(2)];
3. That a substantial part of the fraudulent scheme was committed from outside the United States [See U.S.S.G. § 2B1.1(b)(8)];
4. That the offense involved the conscious or reckless risk of death or serious bodily injury [See U.S.S.G. § 2B1.1(b)(11)]; and
5. That the defendant was an organizer and leader of a criminal activity that involved five or more participants and was otherwise extensive. [U.S.S.G. § 3B1.1(a).]

For purposes of determining defendant SHAFFER'S sentence under the United States Sentencing Guidelines, the Grand Jury alleges the following as to Count One through Count Four of this Indictment:

\$400,000 MMc *10*

1. That the loss exceeded more than \$1,000,000 [See U.S.S.G. § 2B1.1(b)(1)];
2. That the offense involved 10 or more victims [See U.S.S.G. § 2B1.1(b)(2)];
3. That a substantial part of the fraudulent scheme was committed from outside the United States [See U.S.S.G. § 2B1.1(b)(8)];
4. That the offense involved the conscious or reckless risk of death or serious bodily injury [See U.S.S.G. § 2B1.1(b)(11)]; and

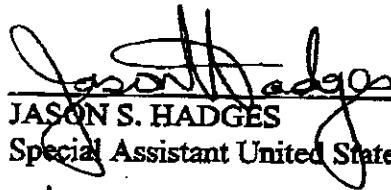
5. That the defendant was an organizer, leader or supervisor in any criminal activity  
[U.S.S.G. § 3B1.1(c).]

A TRUE BILL

  
\_\_\_\_\_  
FOREPERSON OF THE GRAND JURY

Date:

JOHNNY SUTTON  
UNITED STATES ATTORNEY  
Western District of Texas

  
\_\_\_\_\_  
JASON S. HEDGES

Special Assistant United States Attorney

  
\_\_\_\_\_  
MICHELLE E. McELROY

Assistant United States Attorney

AO 42 (Rev. 11/94) Warrant for Arrest

# UNITED STATES DISTRICT COURT

## WESTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA

v.

LINDA SHAFFER

### WARRANT FOR ARREST

CASE NUMBER: A-04-CR-266(2)LY

TO: The United States Marshal  
and any Authorized United States Officer

YOU ARE HEREBY COMMANDED to arrest: LINDA SHAFFER and bring him/her forthwith to the nearest magistrate to answer a(n) INDICTMENT charging him/her with (brief description of offense):

Conspiracy to Distribute hGH for Unauthorized Use and Introduction of Misbranded Drugs;  
Misbranded Drug

in violation of Title 18 & 21 United States Code, Section(s) 371 & 333 & 331

WILLIAM G. PUTNICKI, Clerk, United States District Court

Name & Title of Issuing Officer

Tencha Damian  
Tencha Damian, Issuing Officer

Date and Location: December 9, 2004 Austin, Texas

Bail fixed at \$ Detention

BY: ROBERT PITMAN, U.S. MAGISTRATE JUDGE  
Name of Judicial Officer

#### RETURN

This warrant was received and executed with the arrest of the above-named defendant at

DATED <u>12/8/04</u> RECEIVED	NAME AND TITLE OF ARRESTING OFFICER <u>JEFFREY R. CHRISTO</u> <u>CF DUSA</u>	SIGNATURE OF ARRESTING OFFICER <u>Jeffrey R. Christo</u>
DATE OF ARREST <u>12/8/04</u>		

**U.S. Department of Justice  
United States Attorney**

OPTIONAL FORM 98 (7-90)

**FAX TRANSMITTAL**# of pages ► C02

To	<u>Jim Arnold</u>	From	<u>STRUCKER</u>
Dept./Agency	<u>DOJ</u>	Phone #	
Fax #	<u>617-748-3673</u>	Fax #	
NSN 7540-01-317-7368		5099-101	
GENERAL SERVICES ADMINISTRATION			

**LED**

7 2004

CLERK, U.S. DISTRICT COURT  
WESTERN DISTRICT OF TEXAS  
BY JK DEPUTY CLERK

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF TEXAS**

UNITED STATES OF AMERICA,

Plaintiff,

v.

LINDA SHAFFER,

Defendant.

**A04 CR 266 LY(2)**  
NO. \_\_\_\_\_

**ORDER FOR BENCH WARRANT  
AND SETTING AMOUNT OF BAIL**

It appearing to the Court that an indictment has been returned against the below named defendant, it is hereby ORDERED that warrant issue for the arrest of said defendant, and bail is hereby fixed in the amount shown below, returnable instanter to the Austin Division of this Court, such bail to be taken by any United States Magistrate Judge.

**Defendant****Amount of Bail****LINDA SHAFFER**

Based upon the request of the U.S. Attorney, it is recommended that the Defendant be detained until a hearing pursuant to 18 U.S.C. § 3142 can be held.

ENTERED at Austin, Texas, this 1<sup>st</sup> day of December, 2004.

Rora  
UNITED STATES MAGISTRATE JUDGE

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